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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS' MOTION AND MEMORANDUM IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT REGARDING PREEMPTION

(Assigned to the Honorable David G. Campbell)

(Oral Argument Requested)

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MOTION

Pursuant to Fed. R. Civ. P. 56(c), Local Rule 56.1, and Case Management Order No. 22 (Doc. 5007), Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") respectfully move this Court for summary judgment as to all of Plaintiffs' claims in Plaintiffs' Master Long and Short Form Complaints (Doc. 364, 1485). Bard is entitled to summary judgment because Plaintiffs' claims are expressly and impliedly preempted by federal law.

This motion is supported by Defendants' Memorandum of Points and Authorities, Separate Statement of Facts ("SSOF"), and the Declarations of Robert Carr and John D. Van Vleet, all of which are filed herewith.

MEMORANDUM OF POINTS AND AUTHORITIES

I. Statement of Undisputed Facts.

Plaintiffs' claims arise from their treatment with a Bard IVC Filter, which is an implantable prescription medical device. Bard marketed several IVC Filters for permanent and retrievable indications. Those involved in this MDL are: the Recovery®, G2®, G2® Express, G2®X, Eclipse™, Meridian®, and Denali® Filters. (SSOF ¶1-2)[1]

Before Bard could market any of its IVC Filters, which are Class II devices, federal law required Bard to obtain FDA clearance through §510(k) of the Medical Device Amendments of 1976 ("MDA"), which amended the Food, Drug, and Cosmetic Act ("FDCA"). (SSOF ¶6.) FDA will clear a Class II medical device only if it determines that the device is "substantially equivalent" to a predicate device. (SSOF ¶7.)[2] As amended by the Safe Medical Devices Act ("SMDA") of 1990,[3] §510(k) requires that a device, such as

[1] Bard is seeking summary judgment for claims related to all of its IVC Filters, with the exception of the Simon Nitinol Filter ("SNF"). The SNF was cleared by FDA in an earlier era, before statutory amendments allowed adoption of the device-specific controls and requirements applied by FDA to Bard's other IVC Filters.

[2] A "predicate device" is either a device legally marketed prior to May 28, 1976, for which premarket approval ("PMA") is not required, or a device reclassified from Class III to Class II or I, or a device which has been found substantially equivalent through the 510(k) process. 21 C.F.R. §807.92(a)(3).

[3] PL 101-629, November 28, 1990, 104 Stat 4511.

Bard's IVC Filters, is "substantially equivalent" only if FDA determines that it has the "same technological characteristics" of a predicate device, *or* receives data demonstrating that "the device ***is as safe and as effective*** as a legally marketed device" and any technological differences "do not raise ***different questions of safety and effectiveness***." 21 U.S.C. §360c(i)(A) (emphasis added); 21 C.F.R. §807.100(b). FDA required such data from Bard for all its IVC Filters, after which Bard obtained FDA clearance.

Unlike many devices brought to the market under 510(k), Bard's IVC Filters were, and continue to be, subject to a more rigorous review by FDA. None of Bard's IVC Filter 510(k) submissions in this MDL were of the minimalist pre-SMDA variety. Instead, FDA required extensive safety and effectiveness data for each one of Bard's IVC Filter 510(k) submissions:

Recovery Filter: For the Recovery Filter, FDA required, among other things, clinical testing, and extensive *in vitro* and biocompatibility testing. (SSOF ¶43-47, 50-52, 55.) Following review of the 510(k), FDA mandated specific revisions to the labeling, as well as additional information in response to specific safety and effectiveness questions regarding the clinical, *in vitro*, and biocompatibility testing and other data. (SSOF ¶56-61, 68-73, 86-88, 92-97, 103-06, 111-12, 114.)

Bard filed its 510(k) premarket notification for the Recovery Filter as a permanent filter on July 10, 2002. (SSOF ¶49.) Before FDA would clear the Recovery Filter, FDA required Bard to provide additional information and detailed responses to 17 separate questions, many involving safety and effectiveness concerns. (SSOF ¶56-61.) Bard provided detailed data in response to FDA's multiple requests. (SSOF ¶63-65, 74-77.) FDA also required Bard to revise the Recovery Filter Instructions for Use ("IFU") and labeling to reflect that the filter was for permanent placement only, which Bard did. (SSOF ¶73, 74, 77.) FDA cleared the device after determining that it was as safe and effective as, and therefore substantially equivalent to, the predicate device. *See* 21 U.S.C. §360c(i)(A). (SSOF ¶78-79.) However, FDA placed a limitation on the substantial equivalence determination, requiring specific language in the labeling warning that "the

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safety and effectiveness of the Recovery Filter for use as a retrievable or temporary filter have not been established." (SSOF ¶80.)

Before Bard's Recovery Filter could be cleared for a retrievable indication, FDA required Bard to submit clinical data supporting the safety and effectiveness of retrievability. (SSOF ¶43-47.) Accordingly, a clinical study regarding retrievability of the Recovery Filter was conducted, and, on April 25, 2003, BPV submitted that clinical data with a new 510(k) submission. (SSOF ¶43-48, 98-100.) FDA reviewed the submission and again determined it required additional information and required further revisions of the labeling before it would clear the device. (SSOF ¶103-06, 111-12, 114.) Bard complied with each request. (SSOF ¶107, 113, 115.) On July 25, 2003, FDA cleared the Recovery Filter as a retrievable device and removed the limitation. (SSOF ¶118.)[4]

G2 Filter: For the G2 Filter, FDA again required, among other things, clinical testing, extensive *in vitro* and biocompatibility testing, and a full (as opposed to abbreviated) 510(k) submission. (SSOF ¶172-73, 182-88, 205-07, 211-14, 217, 361, 364.) Following review of the 510(k), FDA mandated specific revisions to the labeling, as well as additional information in response to the clinical study and specific safety and effectiveness questions regarding the *in vivo* animal testing. (SSOF ¶189-91, 215, 221-29, 233, 236-239, 247-48, 253-55.) FDA even required Bard to change the trade name of the device for safety and effectiveness reasons. (SSOF ¶230-31, 240-43.)

Bard filed a 510(k) on March 2, 2005, seeking clearance for a modified Recovery Filter (subsequently known as the G2 Filter), intended to improve resistance to filter fracture and migration. (SSOF ¶170-71.) Before FDA would clear the G2 Filter as a retrievable device, FDA required Bard to conduct an IDE clinical trial called the EVEREST study. (SSOF ¶182-88, 205-07, 211-13.) Bard converted the initial 510(k) submission to a "Traditional" 510(k) for clearance of the G2 Filter as only a permanent

[4] FDA was already heavily involved in revising the labeling before the second 510(k). (SSOF ¶82-97.) Post-marketing, FDA was heavily involved in post-market revisions of the labeling and a Dear Doctor Letter that Bard planned to send, as well as post-market review of a Dear Colleague Letter. (SSOF ¶119-69, 180-81, 210.)

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filter while Bard worked with FDA to develop the EVEREST study. (SSOF ¶217-18.) After Bard provided all additional information required by the agency, FDA cleared the G2 Filter as a permanent filter and placed the same substantial equivalence limitation as it had with the original Recovery Filter – requiring Bard to include specific language that "the safety and effectiveness of the G2 Filter for use as a retrievable or temporary filter have not been established." (SSOF ¶260-61.)[5]

Between 2005 to 2008, Bard and FDA exchanged numerous communications concerning the status and progress of the clinical trial. (SSOF ¶262-307.) FDA demanded information about adverse events observed during the trial. (SSOF ¶290-97.) At the conclusion of the EVEREST study, Bard filed a 510(k) seeking clearance for the G2 Filter as a retrievable device. (SSOF ¶360.) FDA reviewed all of the data from the clinical study and information concerning adverse events observed during the trial and cleared the G2 Filter as safe and effective for retrievability on January 15, 2008. (SSOF ¶368.)

G2 Express Filter: For the G2 Express Filter, FDA required, among other things, *in vitro* and biocompatibility testing. (SSOF ¶372, 375-76.) Following an initial review of the 510(k), FDA required additional biocompatibility testing and additional information in response to FDA's safety and effectiveness concerns regarding the biocompatibility testing. (SSOF ¶380-85, 394-98.)

Bard developed the G2 Express Filter, which slightly modified the G2 Filter by adding a snarable tip, to allow retrieval with other commercially available snares. (SSOF ¶370.) On March 7, 2008, Bard filed a 510(k) seeking clearance of the G2 Express Filter. (SSOF ¶369.) After reviewing the submission, FDA again required additional information before it would clear the device—requiring Bard to perform additional biocompatibility testing. (SSOF ¶380-85, 394-98.) After corresponding with FDA on multiple occasions, Bard complied with FDA's multiple demands for additional biocompatibility testing and

[5] Bard subsequently made changes to the delivery systems of the G2 Filter, and FDA cleared those changes after Bard provided additional testing and risk analysis information that FDA required during its review to address safety and effectiveness concerns. (SSOF ¶308-54.)

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other information. (SSOF ¶386-93, 399-404.) FDA cleared the G2 Express Filter on July 30, 2008, after finding it as safe and effective as, and therefore substantially equivalent to, the G2 Filter. (SSOF ¶405.)

G2X Filter: For the G2X Filter, FDA required, among other things, *in vitro* and biocompatibility testing. (SSOF ¶408, 411.) Following review of the 510(k), FDA required additional information in response to specific safety and effectiveness questions regarding the *in vitro* and biocompatibility testing. (SSOF ¶415-20.)

Bard made further design changes to the delivery systems of the G2 Express Filter and sought 510(k) clearance for these changes as a new device, the G2X Filter, on August 12, 2008. (SSOF ¶406-07.) After reviewing the submission, FDA again required additional information before it could clear the device, which Bard provided. (SSOF ¶415-24.) FDA cleared the G2X Filter on October 31, 2008, after finding it as safe and effective as, and therefore substantially equivalent to, the G2 Express Filter. (SSOF ¶425.)

Eclipse Filter: For the Eclipse Filter, FDA required, among other things, *in vitro* testing and biocompatibility testing. (SSOF ¶434, 437, 457.) Following review of the 510(k), FDA required additional testing for radial force, migration/clot trapping, and tensile strength, as well as specific revisions to the labeling. (SSOF ¶441-44, 460-64.)

Bard developed the Eclipse Filter to improve the surface finish by electropolishing the wire prior to forming the filter. (SSOF ¶426, 433.) After conferring with FDA about these modifications, Bard filed a 510(k) seeking clearance for the Eclipse Filter on November 23, 2009. (SSOF ¶426-32.) FDA reviewed the submission but before it would clear the device, FDA required Bard to conduct additional testing for radial force, tensile strength, and migration/clot trapping, which Bard did. (SSOF ¶441-46.) FDA cleared the Eclipse Filter on January 14, 2010, after finding it substantially equivalent to the G2X Filter. (SSOF ¶447.) Bard later made subsequent changes to the device labeling to add a patient brochure and implant card, and sought clearance for these changes on May 20, 2010. (SSOF ¶448-53.) FDA reviewed that submission, again required additional information, and edited Bard's proposed labeling. (SSOF ¶460-66.) After Bard revised the

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label and provided the additional information, FDA cleared the device on June 25, 2010, finding it as safe and effective as, and thus substantially equivalent to, the G2X Filter. (SSOF ¶467-71.)

Meridian Filter: For the Meridian Filter, FDA required, among other things, extensive *in vitro*, *in vivo* animal, and biocompatibility testing. (SSOF ¶485-91, 577-78.) Following review of the 510(k), FDA required additional *in vitro* testing, specific revisions to the labeling, as well as additional information in response to specific safety and effectiveness questions regarding the *in vitro*, *in vivo* animal, and biocompatibility testing and other data. (SSOF ¶492-504, 508-09, 521-32, 538-39, 545-56, 567, 571-72, 579-83.)

Bard initiated discussions with FDA regarding the Meridian Filter starting in August 2009. (SSOF ¶472.) Even before Bard submitted its clearance application for that device, Bard and FDA discussed FDA's expectations and requirements for Bard's pre-market testing. (SSOF ¶475-83.) In January 2010, FDA provided Bard with certain requirements Bard must meet with regard to animal testing for the Meridian Filter. (SSOF ¶478-82.) Bard submitted its 510(k) submission for the Meridian Filter on August 31, 2010. (SSOF ¶484.) Over the next year, FDA reviewed Bard's submission, and sent Bard 27 different questions requiring a response before FDA could assess potential clearance of the device. (SSOF ¶492-504, 508-09, 521-32, 538-39, 545-56, 567, 571-72, 579-83.) On numerous points, FDA required Bard to conduct additional testing or analyses. (SSOF ¶494-98, 524, 528-29, 538-39, 545-49, 552-55.) To address FDA's "safety concerns," FDA required Bard to conduct additional corrosion resistance testing. (SSOF ¶524.) FDA imposed numerous changes to Bard's labeling and IFU. (SSOF ¶502, 530, 550, 556, 571-72.) After almost a year, and once FDA was satisfied with Bard's responses to FDA's questions, FDA cleared the Meridian Filter on August 24, 2011, finding it as safe and effective as, and thus substantially equivalent to, the G2X Filter. (SSOF ¶573-74.)

Denali Filter: For the Denali Filter, FDA required, among other things, clinical testing, and extensive *in vitro*, *in vivo* animal, and biocompatibility testing. (SSOF ¶602-

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08, 611-12, 616, 622-24, 736-45, 793.) Following review of the 510(k), FDA required specific revisions to the labeling, additional *in vitro* and biocompatibility testing, as well as additional information in response to specific safety and effectiveness questions regarding the clinical, *in vitro*, *in vivo* animal, and biocompatibility testing and other data and analyses. (SSOF ¶627-708, 752-61, 768-71, 776-79, 781-82.)

Bard began discussions with FDA regarding the Denali Filter in August 2009, almost 4 years before FDA cleared the device. (SSOF ¶588.) By May 2010, FDA told Bard that FDA would require Bard to conduct a clinical trial on the Denali Filter before clearing it either as a permanent or retrievable device. (SSOF ¶602-08.) FDA required this clinical trial because of "the increasing literature and clinical practice uncovering filter complications and new risks." (SSOF ¶612.) Bard and FDA worked closely together so that Bard's clinical study protocol met FDA's requirements and expectations as appropriate to support clearance of the Denali Filter. (SSOF ¶613-734.) During the course of this clinical investigation, Bard provided FDA with extensive information concerning the safety and effectiveness of the Denali Filter, including all of the data from the clinical study, which FDA reviewed prior to clearing the device in May 2013. (SSOF ¶706-709, 717-90, 795-818.)

FDA extensively reviewed all of Bard's IVC Filter 510(k) submissions prior to clearing the devices.[6] In all but one review,[7] FDA invoked its statutory power to require additional "safety and effectiveness" information from Bard as a condition for clearance. (SSOF ¶56-61, 68-73, 86-88, 92-97, 103-06, 111-12, 114, 189-91, 215, 221-31, 233, 236-239, 240-43, 247-48, 253-55, 380-85, 394-98, 415-20, 441-44, 460-64, 492-504, 508-09,

[6] It took FDA considerable time to review each filter submission: Recovery (4 ½ months for permanent, 3 months for retrievable), G2 (almost 6 months for permanent, 2 years 6 months for retrievable from submission of IDE), G2 Express (4 ½ months), G2X (2 ½ months) Eclipse (just under 2 months), Meridian (almost 1 year), Denali (2 years 5 months from submission of IDE); a far cry from the outdated 20-hour average cited in *Medtronic v. Lohr*, 518 U.S. 470, 478 (1996).

[7] After reviewing Bard's 510(k) submission for minor modifications to the G2 Femoral Delivery Kit (not the filter itself), FDA cleared the device without requiring additional information. (SSOF ¶354.)

521-32, 538-39, 545-56, 567, 571-72, 579-83, 627-708, 752-61, 768-71, 776-79, 781-82.) If Bard failed to provide this information, FDA would consider the 510(k) withdrawn, pursuant to 21 C.F.R. §807.87(l). (SSOF ¶17, 58, 70, 187, 238, 382, 387, 398, 402, 420, 444, 462, 504, 532, 583.) All of Bard's IVC Filters were designed and tested in conformance with the special controls imposed on IVC Filter manufacturers pursuant to 21 C.F.R. §§870.3375 and 820.30. (SSOF ¶28-38, 51-52, 174-77, 312-15, 349-50, 363-64, 374-76, 410-11, 436-37, 454, 487.)[8] FDA repeatedly required Bard to conduct additional testing. (SSOF ¶384-85, 396, 442, 494-98, 524, 528-29, 538-39, 545-49, 552-55, 636-39, 661-62, 671.) All of Bard's 510(k) submissions also included proposed labeling in conformance with 21 C.F.R. §807.87(e). (SSOF ¶53, 84, 101, 178, 219, 316, 352, 366, 378, 413, 439, 458, 502, 754.) FDA repeatedly imposed specific labeling language as a prerequisite to clearance. (SSOF ¶73, 74, 77, 80, 82-97, 103, 111-12, 114, 190-91, 215, 227-31, 240, 253-55, 261, 463-64, 502, 530, 550, 556, 571-72, 640, 699, 754-58, 771, 776-77.) Pursuant to the SMDA and 21 C.F.R. §807.92, each of Bard's 510(k) submissions included "safety and effectiveness" information upon which the substantial equivalence determination was based. (SSOF ¶54, 102, 51-52, 179, 317, 353, 367, 379, 414, 440, 459, 739-40.) Bard complied with all of these FDA requirements and obtained FDA clearance for each of its IVC Filters. (SSOF ¶78, 118, 260, 343, 354, 368, 405, 425, 447, 471, 573, 587, 783, 794.) All of Bard's IVC Filters were designed, manufactured, packaged, labeled, and sold according to the terms of the FDA clearance through the 510(k) process. (SSOF ¶2.)

As described below, unlike with most 510(k) devices, FDA's rigorous review of Bard's IVC Filters imposed specific requirements on these devices that preempt Plaintiffs' product liability claims.

[8] These requirements were detailed in: Guidance for Cardiovascular Intravascular Filter 510(k) Submissions (FDA Nov. 26, 1999); 510(k) Sterility Review Guidance & Revision (FDA Feb. 12, 1990); Design Control Guidance for Medical Device Manufacturers (FDA Mar. 11, 1997). In addition, FDA required Bard to follow ISO 10993 Biological Evaluation of Medical Devices Part I: Evaluation and Testing.

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II. Argument.

A. Summary Judgment Standard.

Summary judgment is appropriate upon showing that "there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *see Jesinger v. Nev. Fed. Credit Union*, 24 F.3d 1127, 1130 (9th Cir. 1994). Where the moving party will have the burden of proof at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. *Southern Calif. Gas. Co. v. City of Santa Ana*, 336 F.3d 885, 888 (9th Cir. 2003).

B. The Preemption Statute and *Lohr*.

Section 360k(a) of the MDA contains express preemption language, which provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. §360k(a).

Despite this provision's seeming clarity, the Supreme Court has "issued a number of opinions that embody 'divergent views' about the proper role of the MDA's preemption provision, a fact that has yielded considerable 'uncertainty' among the lower courts." *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1337 (10th Cir. 2015), *cert. denied*, 136 S. Ct. 796 (2016) (Gorsuch, J.) (citations omitted).[9] As this Court explained, "the Supreme Court outlined a two-part test to determine whether state law claims are expressly preempted under §360k: (1) whether the federal government established 'requirements' applicable to the device in question, and, if so, (2) whether the state

[9] A number of courts have found tension between *Medtronic v. Lohr* and later Supreme Court preemption decisions, and suggested that "perhaps some of those rules warrant revisiting and reconciliation." *Caplinger*, 784 F.3d at 1340.

common law claims are based on state law requirements 'that are different from, or in addition to the federal ones' and 'relate to safety and effectiveness.'" *Arvizu v. Medtronic Inc.*, 41 F. Supp. 3d 783, 787 (D. Ariz. 2014) (citing *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008)).

In *Medtronic, Inc. v. Lohr*, the Supreme Court held that the 510(k) process – as it existed when the device at issue was cleared in 1982 – did not satisfy the first step, as 510(k) did not impose device-specific federal requirements on the *Lohr* device. 518 U.S. 470, 503 (1996). *Lohr* relied heavily on a presumption against preemption in construing the scope of §360k(a). *Id.* at 485. While state tort requirements "might be 'different from' the federal rules in a literal sense," *Lohr* did not apply §360k(a) literally. *Id.* at 495. Instead, the 510(k) process at issue in *Lohr* did not preempt design claims because it "did not 'require' [the device] to take any particular form for any particular reason." *Id.* at 493-94. Nor were general labeling and manufacturing regulations that were applicable to all medical devices preemptive, because they "reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements." *Id.* at 501.

> The generality of those requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.

Id. Federal medical device requirements, *Lohr* held, are preemptive "only if they are specific counterpart regulations or specific to a particular device." *Id.* at 500. Preemption thus "required a ***careful comparison*** between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement." *Id.* (emphasis added); *see Riegel*, 552 U.S. at 322 (emphasis added) ("[N]o pre-emption occurred in [*Lohr*] based on a ***careful comparison*** between the state and federal duties at issue.").

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In 1990, Congress thoroughly overhauled the 510(k) process by passing the SMDA. Key to the SMDA was section 12, which became 21 U.S.C. §360c(i)(A) – the provision under which all of Bard's IVC Filters were cleared. This section gave FDA broad new powers to require submission of data specifically related to "safety and effectiveness" in order to confirm that newly cleared devices were as safe and effective as their predicates. This section authorized FDA to impose "special controls" on device manufacturers that provide reasonable assurance of the safety and effectiveness of some devices. 21 C.F.R. §860.3. The section further authorized FDA to add design controls to its current good manufacturing practices regulation. 21 C.F.R. §820.30.

The Supreme Court revisited *Lohr* in *Riegel*, 552 U.S. 312. Unlike the 510(k) process described in *Lohr*, the Court in *Riegel* held that the premarket approval ("PMA") process did satisfy the first step of §360k(a), as it imposed device-specific federal requirements. *Id.* at 322-23. That process was not, as in *Lohr*, an exception to FDA safety and effectiveness review – it "is federal safety review." *Id.* at 323. Where FDA allows "almost no deviations from the specifications in its approval" and "the approved form [of the device] provides a reasonable assurance of safety and effectiveness," FDA's decision that the device may be marketed is preemptive. *Id.* The *Riegel* court further held that safety and effectiveness were the very subjects of the plaintiff's common-law claims for defective design, manufacture, and labeling and that such claims were preempted because they imposed requirements "different from, or in addition to," FDA's requirements. *Id.*

Since *Lohr*, courts have often declined to hold claims preempted where medical devices were cleared under the 510(k) process, as opposed to the PMA process. Such decisions typically rely on *Lohr*'s holdings concerning the nature of the pre-SMDA 510(k) process and do not conduct a "careful comparison" of FDA's exercise of its expanded discretionary powers under the 1990 amendments – often because the necessary record was not before the court.

However, *Lohr* nowhere held that the 510(k) process can ***never*** impose preemptive device-specific federal requirements on a medical device. Justice Breyer, whose vote was

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necessary to the majority in the relevant portions of *Lohr*,[10] specifically opined that "the MDA will sometimes pre-empt a state-law tort suit," concerning a 510(k) device. 518 U.S. at 503. "[I]n the absence of a clear congressional command," he looked to what regulations FDA had in effect at the time and found that none of them were "'specific' in any relevant sense." *Id.* at 506-07. For this reason, after "a careful comparison between the state and federal duties at issue," he cast the deciding vote and "held that no pre-emption occurred in [*Lohr*]." *Riegel*, 552 U.S. at 322.

With respect to post-SMDA devices of the sort here, therefore, neither *Lohr* nor *Riegel* provide the answer, although they do provide the relevant framework. Under *Lohr*, FDA's regulatory actions must be "specific" to a device to be preemptive and require "careful comparison" to the state tort duties. Under *Riegel*, preemption exists where the applicable FDA regulatory scheme provides "safety review" and the applicable FDA evaluative process precludes "deviations" from FDA requirements and "provides a reasonable assurance of safety and effectiveness."

Furthermore, the presumption against preemption that guided the majority in *Lohr* no longer exists in express preemption cases such as this. Last year, the Supreme Court abolished anti-preemption presumptions where Congress has included language expressly addressing preemption:

> The plain text of the [preemption clause] begins and ends our analysis. . . . And because the statute contains an express pre-emption clause, we do not invoke any presumption against pre-emption but instead focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.

Puerto Rico v. Franklin California Tax-Free Trust, ___ U.S. ___, 136 S. Ct. 1938, 1946

[10] The holdings in *Lohr* not involving allegations of FDCA violations were 5-4. "When a fragmented Court decides a case and no single rationale explaining the result enjoys the assent of five Justices, the holding of the Court may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds." *Marks v. United States*, 430 U.S. 188, 193 (1977). *See United States v. Davis*, 825 F.3d 1014, 1021-22 (9th Cir. 2016) ("[a] fractured Supreme Court decision should only bind the federal courts of appeal when a majority of the Justices agree upon a single underlying rationale").

(2016) (internal quotations omitted); *accord Atay v. Cty. of Maui*, 842 F.3d 688, 699 (9th Cir. 2016) (following *Franklin* and rejecting presumption against preemption in express preemption case). Thus the analysis in *Riegel*, which did not rely on any anti-preemption presumption in applying §360k(a), is to be preferred over *Lohr*'s more cramped analysis, which is based on a no-longer-available presumption.

Here, the post-SMDA 510(k) process examined both equivalence (*Lohr*) and safety and effectiveness (*Riegel*). For preemption to exist, "a device must undergo the premarket approval process– or, the court [in *Lohr*] suggested, perhaps something like it." *Caplinger*, 784 F.3d at 1340. While "*Lohr* told us little" about "what sort of device-specific regulations beyond the [PMA] process might bear" preemptive effect, some courts have addressed this question. *Id.* at 1339. Indeed, as this Court has recognized in the past,[11] the Ninth Circuit addressed this very issue in *Degelmannn v. Advanced Med. Optics, Inc.*, 659 F.3d 835, 841 (9th Cir. 2011), *vacated*, 699 F.3d 1103 (9th Cir. 2012) ("The fact that lens solution is a Class II device that has come to market via the §510(k) process, as opposed to the PMA process, does not necessarily determine whether it is subject to federal 'requirements' for the purpose of §360k.").[12] The Ninth Circuit has recognized that there are circumstances, consistent with *Lohr*, where FDA has, in a device-specific manner, imposed preemptive federal requirements on a medical device cleared under 510(k). *See, e.g.*, *Degelmannn*, 659 F.3d at 841-42; *Papike v. Tambrands Inc.*, 107 F.3d 737, 742 (9th Cir. 1997) ("This result is entirely consistent with *Medtronic*, which did not involve device-specific federal requirements.").

As described below, a "careful comparison" of the regulatory history of Bard's FDA-cleared IVC Filters demonstrates that FDA did impose the type of device-specific

[11] *Placencia v. I-Flow Corp.*, No. CV10-2520 PHX DGC, 2012 WL 5877624, at *5 n.3 (D. Ariz. Nov. 20, 2012) (finding no preemption where defendant failed to identify an FDA directive comparable to the "specific and detailed directive the FDA issued for" the device in *Degelmann*).

[12] *Degelmann* was later vacated because the parties settled and voluntarily dismissed the appeal, and is therefore no longer precedential. However, the Ninth Circuit's analysis remains instructive in the absence of other, binding authority.

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federal requirements envisioned by Justice Breyer on these devices under the "safety and effectiveness" provisions of 21 U.S.C. §360c(i)(A), as well as post-SMDA regulations and FDA guidance documents. Plaintiffs' common-law claims would impose state requirements "different from or in addition to" those federal FDA requirements. Therefore, Plaintiffs' claims are preempted under §360k(a).

C. Summary Judgment Is Warranted Because Plaintiffs' Claims Are Expressly Preempted Under §360k(a) of the FDCA.

1. The Statutory and Regulatory Framework of 510(k) Has Evolved Significantly Since the *Lohr* Device Was Cleared For Use and Now Imposes Device-Specific Federal Requirements.[13]

The modern 510(k) program now affords FDA discretion to impose device-specific requirements (as the Supreme Court interpreted that term) on medical device manufacturers. The Supreme Court's discussion of the 510(k) process in *Lohr* addressed an already outdated version of the 510(k) program. In *Lohr*, the Court considered the 510(k) program as of November 1982 when FDA cleared the 510(k) device at issue. The device in *Riegel* was approved "in the mid-1990s,"[14] but was a pre-market approved product, so *Riegel* had no occasion to revisit the prior discussion of the 510(k) process in *Lohr*. Thus, the statutory and regulatory framework in those cases did not include the impact of the SMDA's revamping of that FDA 510(k) review.

The 510(k) program has changed greatly since *Lohr*. Not until 1986, after the *Lohr* device was cleared, did FDA formally articulate the factors it would consider during substantial equivalence determinations. (SSOF ¶10.) In 1990, Congress dramatically altered the 510(k) process in section 12 of the SMDA. Section 12 "essentially rewrote the

[13] Bard's argument has not been frequently made or analyzed completely by the courts. Courts that have addressed it either lacked sufficient evidence to analyze the issue, *see, e.g., Horrillo v. Cook Inc.*, No. 08-60931-CIV, 2014 WL 8186704, at *3 (S.D. Fla. June 6, 2014), or are unpersuasive following FDA's more recent interpretation of the evolution of the 510(k) process concerning its "safety and effectiveness" requirements. *See Hovey v. Cook Inc.*, 97 F. Supp. 3d 836, 846 (S.D.W. Va. 2015); *Bellew v. Ethicon, Inc.*, C.A. No. 2:13-cv-22473, 2014 WL 6674424, at *6-7 (S.D.W.Va. Nov. 24, 2014); *Sanchez v. Boston Sci. Corp.*, 38 F. Supp. 3d 727, 744 (S.D.W. Va. 2014).

[14] *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 107 (2d Cir. 2006), *aff'd*, 552 U.S. 312 (2008).

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510(k) process."[15] The new statutory language codified FDA's substantial equivalence definition from the K86-3 Guidance and added several new requirements for 510(k) submissions. *See* 21 U.S.C. §360c(i)(1)(A) (added by SMDA §12). The language expressly linked FDA substantial findings to "safety" and "efficacy"/"effectiveness":

> [T]he term "substantially equivalent" or "substantial equivalence" means . . . that the device . . . (ii)(1) has different technological characteristics and the information submitted . . . contains information, ***including clinical data if deemed necessary by the Secretary***, that demonstrates that the device is as ***safe and effective*** as a legally marketed device, and (II) does not raise different questions of ***safety and efficacy*** than the predicate device.
>
> * * * *
>
> As part of a submission under section 510(k) respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting ***safety and effectiveness***. . . .

PL 101-629 §12 (emphasis added). Given that the *Lohr* device was cleared by FDA prior to 1990, that decision only mentioned the SMDA in passing and had no reason to analyze preemption under the post-SMDA regulatory system applicable here – where FDA repeatedly exercised its discretion to require "clinical data" and to impose explicit "safety and effectiveness" requirements on Bard's IVC Filters, such as specific types of testing data and labeling.

Equally important, the SMDA added special controls to the definition of Class II devices. Earlier this year, FDA reiterated that "[s]pecial controls are device-specific." (SSOF ¶26.).[16] The original 1976 definition of Class II devices in the MDA "identified performance standards ***rather than special controls*** as the mechanism by which FDA could establish reasonable assurance of safety and effectiveness." (SSOF ¶24.) (emphasis

[15] Ralph F. Hall & Michelle Mercer, *Rethinking* Lohr*: Does "SE" Mean Safe and Effective, Substantially Equivalent, or Both?*, 13 MINN. J.L. SCI. & TECH. 737, 748 (2012).

[16] *See also* FDA, *Regulatory Controls (Medical Devices)*, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm2005378.htm (last updated June 26, 2014) ("Special controls are regulatory ***requirements*** for class II devices.") (emphasis added).

added). While the device in *Lohr* was "subject only to the general control provisions of the Act," 518 U.S. at 480, the SMDA changed this, adding "special controls" to FDA's arsenal, that can include "promulgation of performance standards as well as postmarket surveillance, patient registries, development and dissemination of guidance documents, and other appropriate actions as FDA deems necessary to provide such assurance." 21 C.F.R. §860.3.

While *Lohr* criticized general controls as being "the lowest level of protection 'applicable to all medical devices,'" 518 U.S. at 493, Congress fixed that in the SMDA, recognizing that general controls and performance standards "by themselves [were] insufficient to provide reasonable assurance of the safety and effectiveness of" some devices. 21 U.S.C. §360c(a)(1)(B).

> This authority gave FDA ***more flexibility*** in identifying the controls necessary to provide reasonable assurance of the ***safety and effectiveness*** of class II devices.

(SSOF ¶25.) (emphasis added). Using special controls, "FDA has issued many ***device-specific*** guidance documents that clarify the data that should be included in 510(k)s for particular device types." (SSOF ¶30.) (emphasis added). These device-specific guidances are intended to address specific risks or issues related to specific devices or device types, and where, as here, FDA has required manufacturers to follow them, they become device-specific federal requirements entitled to preemptive effect. *Degelmann*, 659 F.3d 835, 842; *Rasheed v. Church & Dwight Co.*, No. 5:11CV80, 2012 WL 262619, at *7-8 (Mag. E.D. Tex. Jan. 12, 2012) (FDA-specified labeling preemptive), *adopted*, 2012 WL 262616 (E.D. Tex. Jan. 30, 2012); *Tuttle v. CIBA Vision Corp.*, No. 2:05-CV-340 TS, 2007 WL 677134, at *2 (D. Utah Mar. 1, 2007) (clearance procedure spelled out in "comprehensive Guidance Document" preemptive); *Whitson v. Safeskin Corp.*, 313 F. Supp. 2d 473, 477 (M.D. Pa. 2004) (device-specific regulatory manual preemptive); *cf. Thompson v. DePuy Orthopaedics, Inc.*, No. 1:13-CV-00602, 2015 WL 7888387, at *9-10 (S.D. Ohio Dec. 4, 2015) (accepting this argument; but "no evidence provided" for device in question).

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The SMDA further authorized FDA to add design controls to its current good manufacturing practices regulation ("CGMPs"). When FDA cleared the *Lohr* device in November 1982, FDA's pre-SMDA good manufacturing practices did not include these design control requirements. "[L]ack of design controls" had been "one of the major causes of device recalls" and "unless appropriate design controls are observed . . . a finished device may be neither safe nor effective for its intended use." Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation, 61 Fed. Reg. 52615 (FDA Oct. 7, 1996). Exercising its expanded SMDA powers, FDA promulgated new Design Control regulations in 1996 requiring device manufacturers to "establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met." 21 C.F.R. §820.30(a)(1). FDA applied these post-*Lohr* design controls to Bard's IVC Filters.

As FDA concluded in its 2010 Working Report, "the 510(k) program has changed significantly since its inception…. Through various statutory and regulatory modifications over time, it has become a ***multifaceted premarket review process that is expected to assure that cleared devices, subject to general and applicable special controls, provide reasonable assurance of safety and effectiveness***, and to facilitate innovation in the medical device industry." (SSOF ¶39.) (emphasis added). Likewise, FDA stated in its 2017 Memorandum:

> Although the 510(k) process involves a comparison of a new device to a predicate device rather than an independent demonstration of the new device's safety and effectiveness . . ., ***in all these cases FDA's review process reflects a determination of the level of control necessary to provide a "reasonable assurance of safety and effectiveness."***

(SSOF ¶19.) (emphasis added).

Thus, the statutory and regulatory framework of 510(k) review has evolved significantly since *Lohr* discussed substantial equivalence. FDA has added device-specific federal requirements that did not exist at the time the agency acted in *Lohr*. Accordingly, *Lohr* does not preclude this Court from holding the claims in this MDL are preempted by

§360k(a), even though they relate to a Class II medical device cleared under §510(k).

2. A "Careful Comparison" of FDA's Actions Demonstrates That the Agency Imposed Device-Specific Federal "Requirements" on Bard's Devices That Did Not Exist in the *Lohr* Scenario.

Bard's IVC Filters are not like most devices brought to the market under 510(k) – even after the SMDA. They were, and continue to be, subject to a more rigorous review by FDA. This extensive regulatory history is discussed above and in the accompanying declarations. During this rigorous review, FDA imposed device-specific federal requirements as to the design, manufacture, testing, and labeling of Bard's IVC Filters. Specifically, FDA required compliance with: special controls specific to IVC Filters; FDA Guidance documents, including a Guidance specific to IVC Filters; demands for extensive clinical testing; specific labeling changes dictated word-for-word by FDA; and numerous requests for additional testing and other information that, if unanswered, would cause FDA to consider Bard's 510(k) submissions withdrawn. As FDA stated on numerous occasions, all of this information was necessary to the agency's evaluation of "safety and effectiveness" in its substantial equivalence determinations.

None of these requirements existed in *Lohr*, and they are more typical of FDA's more rigorous PMA process. *See, e.g.*, *Horn v. Thoratec Corp.*, 376 F.3d 163, 170 (3d Cir. 2004) (discussing "mandatory conditions"—created by "correspondence, clinical testing and device alteration"—pertaining to "manufacturing, packaging, storage, labeling, distribution and advertising"). Unlike the generic federal requirements in *Lohr*, the specific requirements FDA imposed on Bard's IVC Filters reflect "the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements." *Lohr*, 518 U.S. at 501. "This, then, ***is*** a case 'in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on

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manufacturers or producers.'" *Papike*, 107 F.3d at 741 (quoting *Lohr*, 518 U.S. at 501). As it should have, FDA mandated the language to appear on Bard's warnings, required IDE and other clinical trials, mandated additional testing, and demanded additional information about all but one[17] design change Bard proposed. These regulatory actions created federal device-specific requirements that are entitled to preemptive effect.

a. FDA required compliance with special controls.

Unlike the device in *Lohr*, FDA imposed special controls on Bard's IVC Filters. *See* 21 C.F.R. §870.3375. Pursuant to this regulation, FDA required Bard to comply with the following in each IVC Filter 510(k) submission:

- ISO 10993 Biological Evaluation of Medical Devices Part I: Evaluation and Testing;
- FDA's 510(k) Sterility Review Guidance and Revision (Feb. 12, 1990) (K90-1); and
- FDA's Guidance for Cardiovascular Intravascular Filter 510(k) Submissions (Nov. 26, 1999).

Id. These requirements represent "device-specific" special controls that FDA determined to be necessary to provide a reasonable assurance of the safety and effectiveness of Bard's IVC Filters. (SSOF ¶26.) Likewise, the Ninth Circuit and other courts have recognized special controls like these to be device-specific requirements. *Degelmann*, 659 F.3d at 842; *Tuttle*, 2007 WL 677134, at *2.

FDA's Guidance for IVC Filter 510(k) Submissions is a "specific and detailed directive the FDA issued" for IVC Filters, similar to the FDA guidances in *Degelmann* and *Tuttle*. *See Placencia v. I-Flow Corp.*, No. CV10-2520 PHX DGC, 2012 WL 5877624, at *5 n.3 (D. Ariz. Nov. 20, 2012) ("*Degelmann* turned on a specific and detailed directive the FDA issued for contact lens solutions passing through the 510(k) approval process"). FDA's Filter Guidance established important preclinical tests and clinical design requirements for these devices, which FDA enforced here. Like the

[17] FDA did not require additional information for the minor changes Bard made to the G2 Femoral Delivery Kit.

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specific testing required by the Contact Lens Care Guidance in *Degelmann*, FDA required Bard to follow the Filter Guidance's requirements to perform biocompatibility testing in accordance with the provisions in ISO 10993 for implantable, blood-clotting devices. (SSOF ¶31.) Bard further performed pre-clinical testing in compliance with the Filter Guidance that FDA concluded adequately addressed the following filter design issues: simulated deployment, introducer/sheath suitability, clot trapping ability, filter fracture, caval perforation/filter migration, thrombogenicity, and MRI compatibility. (SSOF ¶32.) Just as in *Degelmann* and *Tuttle* − indeed just as in many PMA submissions − Bard's Filter 510(k) submissions undisputedly included extensive bench testing conducted in accordance with this Guidance. (SSOF ¶50, 174, 311, 346, 361, 372, 408, 434, 454, 485, 577, 736, 793.) In each of Bard's 510(k) submissions, it identified this Guidance as one of the special controls it was following. (SSOF ¶51, 173-177, 312-15, 349-50, 363-64, 374-76, 410-11, 436-37, 454, 487.) FDA would not have cleared the devices had Bard not complied with this Guidance, producing results to demonstrate that Bard's IVC Filters were as "safe and effective" as their predicate devices. Therefore, like in *Degelmann* and *Tuttle*, these special controls are device-specific federal requirements entitled to preemptive effect. *Id.*

b. FDA required Bard to conduct clinical studies of its Filters.

Unlike the device in *Lohr* – and unlike the vast majority of even post-SMDA 510(k) submissions – many of Bard's IVC Filter submissions were supported by clinical data.[18] FDA specifically ***required*** Bard to conduct clinical testing on the Recovery, G2, and Denali Filters, and required Bard to include the clinical data generated by those studies in the 510(k) submissions for those devices. FDA required Bard to conduct IDE clinical trials, a process also recognized as device-specific and therefore preemptive. *See*,

[18] "Only approximately eight percent of 510(k)s for non–in-vitro-diagnostic devices contain clinical data, and only 11 percent of these 510(k)s reference a predicate for which clinical data was provided. Less than one percent of non–in-vitro-diagnostic 510(k)s reference a clinical trial conducted under an approved Investigational Device Exemption application (IDE)." (SSOF ¶16.)

e.g., *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 227 (6th Cir. 2000) (finding "no material difference" between the IDE and PMA processes); *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090, 1097 (6th Cir. 1997) ("the regulations governing investigational devices are essentially device specific"); *Parks v. Howmedica Osteonics Corp.*, No. 8:15-CV-0075-MSS-MAP, 2016 WL 7220707, at *7 (M.D. Fla. Mar. 11, 2016) (the "approval process under the IDE is device specific").

Under the SMDA, FDA has this power. If FDA determines clinical data is necessary, it may require such data in a 510(k) submission. 21 U.S.C. §360c(i)(1)(A)(ii); 21 C.F.R. §860.3. When clinical data is provided in the 510(k) submission it "should constitute valid scientific evidence as defined in 21 C.F.R. §860.7(c)(2) and must comply with the Investigational Device Exemptions (IDE) regulations as applicable." (SSOF ¶15.) The Filter Guidance warned that human clinical investigations could be necessary for new IVC filter designs or even for modified filter designs. (SSOF ¶35.) It further identified specific complications that Bard had to analyze during its clinical investigation. (SSOF ¶36.) Historically, clinical data were only required for PMA devices and were certainly *not* required for the *Lohr* device. Courts have found, albeit in other contexts, that an FDA requirement of extensive clinical trials is a device-specific requirement with preemptive effect. *E.g.*, *Horn*, 376 F.3d at 169-70; *Kemp*, 231 F.3d at 225; *Martin*, 105 F.3d at 1097. The requirement of clinical testing is necessarily device-specific, and reflects "the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements." *Lohr*, 518 U.S. at 501.

In *Horn*, a decision that predated but foreshadowed *Riegel*, the Third Circuit held that the requirements FDA imposed on the defendant's PMA device were "precisely 'the sort of concerns regarding a specific device' which the Supreme Court intimated would give rise to preemption under §360k(a)." *Id.* Device-specific requirements were "created through a decades-long process of correspondence, clinical testing and device alteration." *Id.* at 170. Specifically, FDA required the defendant to conduct clinical trials of its device

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under an IDE. *Id.* at 169. During the clinical study, the defendant "submitted more than ninety supplements to the FDA, and the FDA made numerous inquiries about the [device] and its clinical trials, including correspondence concerning" adverse events experienced during the trial. *Id.* at 170. After extensive review of the defendants' PMA application, FDA approved the device. *Id.* The Third Circuit held that these device-specific federal requirements preempted plaintiff's claims. *Id.* at 180.

The regulatory record here is similar to *Horn*. FDA, exercising its SMDA authority, required Bard to conduct clinical studies on the Recovery, G2, and Denali Filters. Regarding the Recovery Filter, FDA required submission of clinical data to support clearance of the device for retrievability. (SSOF ¶43-47.) In response to FDA's demand, a clinical study was conducted for the Recovery Filter, and that clinical data was used to support Bard's 510(k) submission for a retrievability indication for the Recovery Filter. (SSOF ¶43-48, 98-100) Likewise, before Bard could receive a retrievable indication for its G2 Filter, FDA required Bard to provide clinical data supporting the safety and effectiveness of long-term retrievability of the device. (SSOF ¶182-88, 205-07, 211-13.) In response to FDA's request for clinical data, Bard conducted an IDE clinical trial called the EVEREST study. (SSOF ¶262-307.) As in *Horn*, during the EVEREST study – taking almost two years to complete – Bard and FDA exchanged numerous communications concerning the trial's status and progress. (SSOF ¶262-307.) The process included inquiries from FDA regarding adverse events observed during the trial, and Bard's responses to those inquiries, as well as information Bard provided regarding clinical effectiveness and success of retrievability. (SSOF ¶290-97.) FDA reviewed all of this information concerning the safety and effectiveness of the G2 Filter, including all of the data from the clinical study, before clearing the device as a retrievable device in 2008. (SSOF ¶368.)

Finally, as a prerequisite to clearance for any indication for the Denali Filter, either permanent or retrievable, FDA required Bard to conduct a multi-center clinical study. (SSOF ¶602-08.) FDA explained that part of the reasoning for requiring Bard to conduct a

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clinical trial was because of the "the increasing literature and clinical practice uncovering filter complications and new risks." (SSOF ¶612.) Bard conferred with FDA multiple times after this meeting to develop the IDE protocol that FDA ultimately approved. (SSOF ¶613-734.) Again, as in *Horn*, Bard submitted numerous clinical information, including safety and effectiveness information over the course of the trial. (SSOF ¶706-709, 717-90, 795-818.) Therefore, as in *Horn*, FDA's requirement that Bard conduct extensive clinical testing of its IVC Filters is a device-specific requirement entitled to preemptive effect.

c. FDA required additional testing, labeling, and other information during its review.

During FDA's review of Bard's IVC Filters, FDA imposed substantial additional requirements on Bard—requiring specific labeling changes, additional testing, further analyses, and additional information necessary to facilitate the agency's determination of substantial equivalence.

For all 510(k) submissions, Bard had to submit proposed labels, labeling, and advertisements for FDA's review. 21 C.F.R. §807.87(e). FDA may require specific statements be included in labeling. 21 U.S.C. §360c(i)(1)(E). The Filter Guidance required Bard to include specific text in its labeling and follow specific label formatting. (SSOF ¶37.) The Ninth Circuit has held that specific warning requirements similar to these are device-specific requirements entitled to preemptive effect. *See Papike*, 107 F.3d at 742.

Beyond the device-specific labeling found in the Filter Guidance, FDA reviewed Bard's labeling in each of its 510(k) submissions, often partially rewriting and making many specific changes to Bard's IVC Filter labels. (SSOF ¶73, 74, 77, 80, 82-97, 103, 111-12, 114, 190-91, 215, 227-31, 240, 253-55, 261, 463-64, 502, 530, 550, 556, 571-72, 640, 699, 754-58, 771, 776-77.) For example, before clearing the G2 Filter in 2005, FDA required Bard to add language to the IFU regarding bariatric patients. (SSOF ¶227.) Similarly, before clearing the Meridian Filter in 2011, and before approving the Denali Filter IDE in 2011, FDA required Bard to include language in its IFU regarding the

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potential for nickel leaching. (SSOF ¶556, 699.) FDA also mandated off-label use warnings for the Recovery and G2 Filters. (SSOF ¶80, 261.) FDA also required Bard to revise its labeling for the Eclipse Filter. (SSOF ¶463-64.) For each of Bard's IVC Filters, FDA cleared the language included on Bard's labeling. (SSOF ¶78, 118, 260, 343, 354, 368, 405, 425, 447, 471, 573, 587, 783, 794.) FDA later reviewed and approved Bard's modifications to the device's labeling. (SSOF ¶123-27, 180-81, 210, 448-53, 463-64.)

Furthermore, during its review of Bard's 510(k) submissions, FDA frequently required Bard to perform additional testing of its filter designs. (SSOF ¶384-85, 396, 442, 494-98, 524, 528-29, 538-39, 545-49, 552-55, 636-39, 661-62, 671.) The Filter Guidance warned that the "***necessary*** array of tests for a particular filter will depend, in part, on the specific design," and that additional pre-clinical testing may be "***necessary to qualify all filters/designs.***" (SSOF ¶33.) FDA's requests for additional testing were often explicitly linked to FDA safety and effectiveness concerns. For example, before FDA would clear the Meridian Filter, to address FDA's "safety concerns" related to Meridian's corrosion resistance, FDA required Bard to perform additional corrosion resistance testing. (SSOF ¶524.) Bard complied with these requirements and performed the additional testing. (SSOF ¶392, 446, 513-19, 540-41, 559, 563-65, 569, 661-63, 677-80.)

FDA also required Bard to provide additional information about the testing and design of its IVC Filters. If Bard failed to provide this information, FDA would consider the 510(k) withdrawn, pursuant to 21 C.F.R. §807.87(l). (SSOF ¶17.) FDA is "empowered to ***require*** additional necessary information" to facilitate the agency's substantial equivalence determinations. *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (citing 21 C.F.R. §870.87(l)) (emphasis added). FDA repeatedly required additional information to fully evaluate the safety and effectiveness of Bard's products. (SSOF ¶56-61, 68-73, 86-88, 92-97, 103-06, 111-12, 114, 189-91, 215, 221-31, 233, 236-239, 240-43, 247-48, 253-55, 380-85, 394-98, 415-20, 441-44, 460-64, 492-504, 508-09, 521-32, 538-39, 545-56, 567, 571-72, 579-83, 627-08, 752-61, 768-71, 776-79, 781-82.) For example, FDA requested Bard to provide additional animal study data regarding the

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Meridian Filter because FDA could not assess Bard's conclusions raised "about the chronic safety of the Meridian filter" based on the animal study test reports provided. (SSOF ¶498.) Additionally, FDA requested Bard to provide additional information demonstrating that "tilting of the Recovery Filter does not affect the effectiveness and safety of the filter." (SSOF ¶60.) Again, for the G2 Filter delivery kit, FDA required Bard to provide additional information about risks associated with the modifications, the testing conducted, and how such testing mitigated the risks so FDA could determine that the modifications "do not affect the safety and effectiveness of the device." (SSOF ¶327-29.)

Unlike the general requirements in *Lohr*, all of these requirements were necessarily device-specific − they constituted specific requirements FDA imposed on Bard before FDA would clear each individual Bard Filter. Accordingly, these requirements reflect "the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements." *Lohr*, 518 U.S. at 501. This, then ***is*** a case "in which the Federal Government [FDA] has weighed the competing interests" and unambiguously resolved those interests in favor of implementing "a specific mandate" on Bard. *Papike*, 107 F.3d at 741 (citing *Lohr*, 518 U.S. at 501). Therefore, these device-specific federal requirements are entitled to preemptive effect.

3. Plaintiffs' State Law Claims Impose Requirements Different From or in Addition to the Device-Specific Federal Requirements Imposed on Bard.

As just demonstrated, FDA imposed device-specific research, design, manufacture, testing, marketing, and labeling requirements on through its detailed review of Bard's 510(k) IVC Filter submissions. Comparing these FDA requirements to Plaintiffs' allegations here requires preemption of those allegations. By enacting §360k(a), Congress expressly preempted any state law claim "different from or in addition to" any and all FDA requirements imposed on the design, manufacturing, testing, marketing, or labeling of these particular products. *Riegel*, 522 U.S. at 326-27; *see Caplinger*, 784 F.3d at 1339

(the preemptive "chapter" in §360k(a) "contains the whole of the FDCA").

As one court stated in the context of PMA devices, since *Riegel*, "courts across the country have applied Section 360k(a) broadly, preempting all manner of claims from strict products liability and negligence, to breach of warranty, to failure to warn and manufacturing- and design-defect, to negligence per se." *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1152 (D. Minn. 2009) (citations omitted), *aff'd*, 623 F.3d 1200 (8th Cir. 2010). Further, the presumption against preemption that led the Court in *Lohr* to apply §360k(a) narrowly no longer exists. *Franklin*, 136 S. Ct. at 1946; *Atay*, 842 F.3d at 699. Plaintiffs' product liability claims would impose requirements different from or in addition to the IVC Filter-specific federal requirements Bard followed, and are thus preempted under §360k(a):

Design and Manufacturing Defect Claims. To prevail on the design or manufacturing defect claims, Plaintiffs would have to establish that Bard's IVC Filters should have been designed or manufactured in a manner different from that cleared by FDA after rigorous review of the clinical and pre-clinical testing of that design.

Warnings-Based Claims. To prevail on the warnings-based claims, Plaintiffs would have to prove that Bard should have provided different or additional warnings from those reviewed and cleared – and, for many of these devices, partially rewritten – by FDA. (SSOF ¶73, 74, 77, 80, 82-97, 103, 111-12, 114, 190-91, 215, 227-31, 240, 253-55, 261, 463-64, 502, 530, 550, 556, 571-72, 640, 699, 754-58, 771, 776-77.) Thus, Plaintiffs' claims that Bard failed to warn them or their physicians "are preempted because they would require Defendants to take actions that are different from or in addition to the requirements imposed by [FDA]." *Arvizu*, 41 F. Supp. 3d at 792 (citing *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013) (Watford, J., concurring, joined by six judges) ("[A]ny attempt to predicate the [claim] on an alleged state law duty to warn doctors directly would have been expressly preempted under" §360k)).

Breach of Warranty Claims. To prevail on the breach of warranty claims, Plaintiffs would have to prove that the device was not safe and effective – or that its

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labeling was deficient− findings that would contrad ict FDA's determination during the 510(k) process that Bard complied with all requirements, and provided all labeling, that FDA deemed sufficient to ensure a reasonable assurance of the device's safety and effectiveness.

Derivative Claims. Plaintiffs' derivative claims for loss of consortium, wrongful death, survival, or negligent infliction of emotional distress, are also preempted because they depend on the success of the underlying claims above which are preempted.

D. Summary Judgment Is Warranted Because Plaintiffs' Claims Are Impliedly Preempted Under the Supreme Court's Conflict-Preemption Principles.

The Supreme Court in *Lohr* left open the possibility that a state common-law action for damages involving a 510(k) cleared device could be impliedly "pre-empted under conflict pre-emption analysis." *Lohr*, 518 U.S. at 503; *see also Buckman*, 531 U.S. at 352 ("[N]either an express pre-emption provision nor a saving clause bars the ordinary working of conflict pre-emption principles.").[19] Federal law preempts state law where it is "not lawful under federal law… to do what state law required." *PLIVA v. Mensing*, 564 U.S. 604, 618 (2011). "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *Id.* at 620. "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 624 (warning claim impliedly preempted where generic drug manufacturer could not independently change product labeling without prior FDA review); *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013) (same regarding design claim).

[19] To the extent that Plaintiffs' state law claims seek to enforce the FDCA and its implementing regulations, they are impliedly preempted under 21 U.S.C. §337(a) because such claims would usurp the FDA's exclusive enforcement authority and thereby conflict with the federal regulatory scheme. *Buckman*, 531 U.S. at 349 n.4 (§337(a) "leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions"); *Perez v. Nidek Co.*, 711 F.3d 1109, 1119 (9th Cir. 2013) (following *Buckman* and holding claim in conflict with enforcement scheme impliedly preempted).

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While *Mensing* and *Bartlett* involved generic drugs and not medical devices, the Supreme Court's analysis was grounded in fundamental implied preemption principles and not limited to generic drug litigation. *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 703-04 (3d Cir. 2016) (applied to airplanes); *Yates v. Ortho-McNeil Pharmaceuticals, Inc.*, 808 F.3d 281, 298 (6th Cir. 2015) (applied to non-generic drugs); *In re Celexa & Lexapro Marketing & Sales Practices Litigation*, 779 F.3d 34, 41 (1st Cir. 2015) (same). Thus, the Supreme Court's impossibility preemption analysis applies with equal weight here.

Indeed, just as federal law prohibited the manufacturers in *Mensing* and *Bartlett* from unilaterally changing the design or labeling of their drugs without prior FDA review, Bard is prohibited from unilaterally modifying or changing its IVC Filters without first submitting a new 510(k) for FDA review if such device-related change would "significantly" change or modify the "design, components, method of manufacture, or intended use" of the device. *See* 21 C.F.R. §807.81(a)(3). A significant change includes a "change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process." 21 C.F.R. §807.81(a)(3)(i). Bard is also prohibited from unilateral labeling changes that significantly impact safety and effectiveness without first submitting a new 510(k). (SSOF ¶38.)

That Bard could not make significant changes to its IVC Filters or the accompanying labels without prior FDA review is borne out by the facts. As to the Recovery Filter, in 2004, Bard proposed to FDA certain changes to the IFU. (SSOF ¶119-23.) FDA stated that it would have to review Bard's proposed labeling changes to see if a new 510(k) would be required. (SSOF ¶123-27.) Ultimately, FDA instructed Bard that no 510(k) would be required. (SSOF ¶135-40.) When Bard proposed changes to the labeling for the Eclipse Filter, FDA required a new 510(k) and ultimately additional labeling changes. (SSOF ¶448-53, 463-64.) Likewise, not only did FDA require Bard to submit a new 510(k) application to support proposed changes to the Denali Filter, but FDA

required Bard to submit a more rigorous and detailed "Traditional" 510(k) application. (SSOF ¶603.)

A tort judgment finding that the design of Bard's IVC Filters did not comport with a state-law duty of due care, or that its labeling did not comport with a duty to warn, would necessarily require labeling or design changes that significantly affect the safety or effectiveness of the device. But if Bard unilaterally changed the labeling or design of its IVC Filters to satisfy its state-law duties, Bard would violate federal law, which expressly requires prior FDA review of these types of changes. *Mensing*, 564 U.S. at 618-19 (labeling changes); *Bartlett*, 133 S. Ct. at 2476 (design changes); *see also Yates*, 808 F.3d at 300 (design defect claims preempted).[20] "Where state law imposes a duty to take such remedial measures, it actually conflicts with federal law by making it impossible for a private party to comply with both state and federal requirements." *Bartlett*, 133 S. Ct. at 2479 (quotations omitted). Here, it would be impossible for Bard "to comply with both [its] state-law duty to change the label [or design] and [its] federal law duty to keep the label [or design] the same" without prior FDA review. *Mensing*, 564 U.S. at 618.[21] Therefore, the Plaintiffs' design and labeling defect claims are impliedly preempted under the Supreme Court's conflict ("impossibility") preemption principles.

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[20] Bard acknowledges that there is contrary authority on this issue. *See Mullins v. Ethicon, Inc.*, 147 F. Supp. 3d 478, 485 (S.D.W. Va. 2015) (rejecting *Mensing-Bartlett* preemption argument for 510(k) device). *Mullins*, however, did not discuss the post-*Bartlett* appellate precedent applying impossibility preemption under the Supreme Court's reasoning to products other than generic drugs, and its expansive view of *Lohr* predated the Supreme Court's rejection of the anti-preemption on which *Lohr* was based.

[21] Nor is Bard required to "stop-selling" its Filters in lieu of making the unilateral labeling or design changes demanded by its state-law duties to avoid this impossibility. *Bartlett*, 133 S. Ct. at 2479 ("We reject this 'stop-selling' rationale as incompatible with our preemption jurisprudence. Our preemption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability."); *Moretti v. Wyeth, Inc.*, 579 Fed. Appx. 563, 565 (9th Cir. 2009) ("*Bartlett* bars claims based on a manufacturer's failure to exit the market").

III. Conclusion.

For these reasons, Defendants request that this Court grant Defendants' Motion.

RESPECTFULLY SUBMITTED this 24th day of March, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of March 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

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